



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

**Environmental Protection Agency
Office of Pesticide Programs
Registration Division
Minor Use and Emergency Response Branch**

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Subject: EPA's Re-evaluation of the FIFRA Section 24(c) Review Process

INTRODUCTION

Section 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) states that "*A state may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs...*" Many of these special local needs (SLN) registrations are for additional uses not authorized by the EPA-approved label, for example, applying the pesticide to a different crop (provided a tolerance exists for that crop) to address an outbreak of disease, adding an alternative application method that suits the practices of that state, or adding a new pest species that is not on the EPA-approved label. However, rather than providing for state registration of additional uses not included on the EPA-approved label, some states issue section 24(c) registrations that are more narrow than the EPA-approved label, for example, adding a more restrictive application cut-off date, adding training and certification requirements, or limiting the number of treatments permitted by the EPA-approved label.

EPA is re-evaluating its section 24(c) review process to clarify whether states may issue SLN registrations which are more restrictive than the federal registration. This document provides background information about FIFRA section 24, describes current practices regarding section 24(c) registrations, identifies concerns about more restrictive section 24(c) registrations, and solicits comments to inform EPA as the Agency re-evaluates its review process on more restrictive section 24(c) registrations.

BACKGROUND

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

FIFRA is the federal statute that governs the registration, distribution, sale, and use of pesticides in the United States. With certain exceptions, a pesticide is any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or

intended for use as a plant regulator, defoliant, or desiccant, or any nitrogen stabilizer. FIFRA generally requires that a pesticide must be registered with the EPA before it may be sold, distributed or used in the United States unless it qualifies for an exemption.

Section 24(a) of FIFRA

The states' authority to regulate pesticides under their own inherent authority (i.e., police power) is limited but not preempted by FIFRA. Section 24(a) of FIFRA provides that "*A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.*" Most states have adopted their own state-specific laws and regulations for pesticides. In such states, even though a given pesticide product may have an EPA-approved registration allowing the distribution and sale of the product within the United States, a state may have additional requirements that must be met before the pesticide product can be distributed, sold, or used within that state. The requirements vary between the states and may include additional data and licensing requirements, or the addition of restrictions on pesticide use within the state's jurisdiction.

Section 24(c) of FIFRA

Section 24(c) of FIFRA provides authority to states to register an additional use of a federally registered pesticide product, or a new end use product, to meet special local needs if certain conditions are met. These registrations (also referred to as "special local needs" registrations) automatically become FIFRA registrations (allowing use only within the authorizing state) unless EPA disapproves the registration within 90 days. SLN registrations most commonly address a pest problem occurring in a particular state that is not being adequately controlled by currently available pesticides.

For more information regarding FIFRA and sections 24(a) and 24(c) of FIFRA, please refer to EPA's website at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-17-state-regulatory-authority>. Guidance on section 24(c) registrations, including instructions to states regarding how to submit section 24(c) registrations to the Agency, can be found at [HYPERLINK "<https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations>"].

EPA REVIEW OF SECTION 24(c) REGISTRATIONS

EPA reviews section 24(c) registrations, and may disapprove them if, among other things, the use is not covered by necessary tolerances; or the use has been previously denied, disapproved, suspended or canceled by the Administrator; or the use has been voluntarily canceled subsequent to a notice concerning health or environmental concerns. In addition, EPA must determine whether the SLN registration meets the requirements of FIFRA, since section 24(c) registrations become federal registrations within 90 days unless EPA objects to them.

EPA currently receives approximately 300 notifications of section 24(c) registrations annually. Many of these SLN registrations are for additional uses not authorized by the EPA-approved label. Examples of common section 24(c) registrations include: authorizing use against a pest species not approved on the EPA-approved label, use of an additional application method, or

applications to a different crop to address a pest outbreak. These types of additional uses clearly fall within the scope of FIFRA section 24(c) for “*A state [to] provide registration for additional uses of federally registered pesticides formulated for distribution and use within the state to meet special local needs...*”

However, there are examples where, rather than registering additional uses not found on the EPA-approved label, some section 24(c) registrations have more restrictions than the EPA-approved label. In the past EPA has generally allowed those registrations (by not disapproving them within 90 days). Examples include the addition of more restrictive cut-off dates, the inclusion of additional training requirements, more stringent restrictions regarding the time of day when the pesticide can be applied and restricting the use directions by limiting the number of treatments permitted by the EPA-approved label.

EPA is re-evaluating the review process for section 24(c) registrations and the consequences of requiring that those restrictions instead be implemented under FIFRA section 24(a). In addition, EPA is asking for comment on why some states use section 24(a) of FIFRA to impose additional restrictions to an EPA-approved label, while other states prefer to use section 24(c).

Section 24(a) of FIFRA allows a state to regulate the sale or use of any federally registered pesticide in the state, but only if the state regulation does not permit any sale or use prohibited by FIFRA. Thus section 24(a) allows states to regulate a pesticide more strictly under state law than EPA has regulated it under federal law. In contrast, section 24(c) of FIFRA allows states to register “additional uses of federally registered pesticides” to meet special local needs within the state. The section 24(c) registrations become federal registrations (albeit valid only in the issuing state) unless disapproved by EPA.

Therefore, one of EPA’s concerns is that by using section 24(c) for SLN registrations with more restrictive label language, rather than using their state authorities allowed under section 24(a), states may be acting (and creating federal registrations) in a manner inconsistent with FIFRA.

EPA is also concerned that having section 24(c) registrations that are more restrictive than the EPA-approved label has the potential to result in confusion, because the less restrictive EPA-approved registration is still in effect and products bearing only the EPA-approved label may still be available in the state. Where a state issues a section 24(c) registration that expands the uses permitted under the 24(c) label, pesticide users have a strong incentive to acquire and follow the 24(c) label. However, where the section 24(c) label is narrower or more restrictive than the EPA-approved label, pesticide users may be able to choose between the more restrictive section 24(c) label and the less restrictive EPA-approved label.

REQUEST FOR COMMENT

EPA is requesting comments and information from state pesticide regulatory agencies, growers, pesticide registrants and other stakeholders to inform the Agency as it re-evaluates its review process for section 24(c) registrations that are more restrictive than the federal

registration.

Specifically, EPA solicits comments on the following:

- What would the impacts be if states relied on FIFRA section 24(a) rather than section 24(c) to impose restrictions to an EPA-approved label?
- Are there other methods states could use to impose restrictions to an EPA-approved label if the option of using section 24(c) of FIFRA is removed?
- Given the apparently complementary authorities of section 24(a) and section 24(c), why are states relying on section 24(c) for more restrictive SLN registrations rather than relying on section 24(a)?

To submit comments in response to this document, please follow the online instructions for submitting comments outlined within the Notice of Availability posted at [[HYPERLINK "http://www.regulations.gov"](http://www.regulations.gov)] under docket identification (ID) number EPA-HQ-OPP-2019-0443. Do not submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. For additional information, you may contact Kable Bo Davis at (703) 306-0415 or [[HYPERLINK "mailto:davis.kable@epa.gov"](mailto:davis.kable@epa.gov)].